

## Interview Summary

Application No.

08/372,676

Applicant(s)

Chatterjee et al

Examiner

Julie E. Reeves, Ph.D.

Group Art Unit

1806



All participants (applicant, applicant's representative, PTO personnel):

(1) Julie E. Reeves, Ph.D.

(3) \_\_\_\_\_

(2) Michael Schiff

(4) \_\_\_\_\_

Date of Interview Oct 22, 1996Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:Agreement ☒ was reached. ☐ was not reached.Claim(s) discussed: newly added claims 42-48

Identification of prior art discussed:

None

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Attorney requested that claims 42-48 be considered for entry by 312 amendment (Paper no 26, Amendment E). Upon consultation with SPE Feisee and SPRE Schwartz, it has been decided that claims 42-43, directed towards methods of making the antibody; claim 48 directed towards a method of detection using the antibody and claims 44-47 directed towards method of producing anti-GD2 antibodies by administering the antibody will be allowed as renumbered claims 16-17, 18 and 19, 21, respectively, and made dependent upon claims 2, 2, 8, 1, 19 and 19, respectively, for the reasons outlined in the attached PTOL-271. The examiner suggested that Claim 47 be submitted in a continuing application. The attorney confirmed that Applicant fully intends to pursue the inventions of claim 47 is a continuing application.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☒ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

The amendment filed 25 September 1996 under 37 CFR 1.312 has been entered in part.

Claim 40, now renumbered as claim 14, has been amended.

New Claims 42, 43 and 48 have been entered as renumbered claims 16, 17 and 18, respectively, and have been amended to dependent upon renumbered claims 2, 2, and 8, respectively.

New Claims 44, 45 and 46 have been entered for the reasons discussed below as renumbered claims 19, 20 and 21 and have been amended to depend upon renumbered claims 1, 19 and 19, respectively.

New Claim 47 has not been entered as discussed below.

Paper no 6 of the application set forth a restriction requirement as follows:

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I Claims 1-4 and 7-9, drawn to an anti-idiotypic antibody which contains an internal image of the ganglioside GD2 antigen, classified in Class 424, subclasses 131.1 and 178.1.

Group II Claims 5-6, drawn to a method of treatment, classified in Class 424, subclass 131.1 and Class 436, subclass 501.

As correctly argued by the Applicant, "The Training Materials for treatment of product and process claims in light of In re Brower and In re Ochiai and 35 U.S.C. 103(b)", dated July 25 1996 indicates that claims to methods of making or using an allowed product are allowable without reopening substantive prosecution, providing they are supported in the specification and contain all the limitations of the product" (page 4, last paragraph).

It is noted that the method of making the product (newly filed claims 42-43, now renumbered as claims 16-17) were not included the claims as originally restricted. Therefore, these claims cannot be strictly "rejoined" under the guidance of 35 U.S.C. 103(b), but have been included as patentable by the Examiner. Similarly, the method of using the product for a method of detection (newly filed claim 48, now renumbered as claim 18) was also not present in the application at the time of the restriction requirement. Further, the method of using the product to produce antibodies to GD2 (newly filed claims 44-46, now renumbered as claims 19-21) were not present in the application at the time of the restriction requirement. Therefore, these claims cannot be strictly "rejoined" under the guidance of 35 U.S.C. 103(b), but have been included as patentable by the Examiner. It is noted that in claim 44, now renumbered as claim 19, the phrase "active immunity" being interpreted as to the production of an antibody response.

The newly drawn claim 47 is directed towards method of using the product antibody for


eliciting an active immunity in an individual suspected of having one of the various cancers listed. This claims would have been included in Group II, method of treatments, in the Restriction Requirement. It is also noted that the claim 47 is limited in scope to that of the allowed product in renumbered claim 1. For those two reasons, the claim is eligible for consideration of rejoinder under the guidance of 35 U.S.C. 103(b).

It is also noted that the new claims have been submitted as an Amendment under 37 CFR 1.312(a). The MPEP recites that 37 CFR 1.312 was never intended to provide a way for the continued prosecution of an application after it has been passed for issue and that a simple statement that the proposed claim is not obviously allowable and a brief reason, such that more than a cursory review of the record is necessary, is required. Claim 47 recites the administration of an antibody for eliciting active immunity to ganglioside GD2, including the production of anti-GD2 antibody, for individuals suspected of having a variety of cancers listed in claim 47. This amendment raise new issues under 35 U.S.C. 112, first paragraph, for failing to provide an enabling disclosure, as one skilled in the art would not know how to raise paratopic antibodies. Clearly the immunization of the 1A7 antibody would result in antibodies that recognize the constant domains as well as the variable domains, and those which do interact with the variable domains may be specific for public or private paratopes for the treatment of cancer. Accordingly, this claim has not been entered and Applicant is urged to file a continuing application to further prosecution of this method of use claim 47.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Reeves, Ph.D., whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1806 via the fax phone number (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Respectfully,

  
Julie E. Reeves, Ph.D.  
(703) 308-7553

  
LILA FEISEE  
PRIMARY EXAMINER  
GROUP 1800